



QUESTIONS AND ANSWERS

Q: How do the toxin levels in *Ariva* compare to cigarettes ?

A: Star believes that not all tobacco products are created equal. There is a substantial difference between the numbers and levels of toxic constituents in smoked, and in smokeless, tobacco products. There are 4,000 chemical constituents in tobacco smoke, 43 of which are known or suspected carcinogens. Smokeless tobacco, however, is not burned and therefore the user is exposed to many fewer carcinogens. Public health authorities have determined that there are only a handful of toxins that are of concern in smokeless tobacco, and of this handful only the nicotine and TSNAs appear to be at levels that are likely to be linked to health problems.

Q: Will health claims be made for *Ariva* ?

A: No, not at this time. We know that research indicates that nitrosamines cause cancer in animals, and that public health authorities consistently have called for the reduction and/or removal of nitrosamines in tobacco products. However, there is currently no proof that lowering nitrosamines will decrease health risk. Additional studies must be undertaken to demonstrate that TSNA reductions in smokeless tobacco leads to reduced risk of oral cancer.

Q: Low tar and nicotine cigarettes were developed with the hope that there would be a decrease in smoking-related diseases. However, many believe that while this effort was initially well intended, many users of such products smoke more or inhale more deeply in order to attain a certain nicotine level – thereby maintaining or increasing their intake of toxins. Many also believe that aggressive marketing of such products and the use of descriptors such as “low”, “light” etc., beguiles smokers into believing that the use of such products is “safer”. Could similar concerns be raised about *Ariva*?

A: Star is well aware of the controversy associated with “low tar and low nicotine” cigarette products. *Ariva*, however, is significantly different in a number of ways:

- a) Unlike cigarettes, *Ariva* is a smokeless tobacco product that contains only a small number of toxins when compared with cigarette smoke.
- b) When cigarettes are burned, they produce hundreds of toxic chemical constituents, at least 43 of which are known to be carcinogens.



- c) Tar reduction is dependent in part on cigarette filtering and other measures such as the ventilation holes in the filter that result in the dilution of the smoke constituents. The smoker may cover the filter holes during smoking and alter their pattern of inhalation. Because of this, the manner in which a person smokes and the degree of inhalation can dramatically affect the intake of smoke constituents into the lungs. However, *Ariva* is a smoke-free product and therefore, the kind of compensation that occurs among smokers does not take place when this product is used. *Ariva* is a tobacco product for smokers when they can't or don't want to smoke. *Ariva* is to be used when it is not possible to smoke a cigarette – for example, in restaurants or on airplanes. *Ariva* is not a smoking cessation product. The level of nicotine contained in an *Ariva* cigarette™ piece is approximately the same as what a smoker obtains from a light cigarette.
- d) Star's overriding message, which is stated clearly on the product packaging, is that the adult consumer's best option is not to start or to quit tobacco use.
- e) While the *Ariva* label will state that it contains StarCured™ tobacco, Star does not currently plan to label or advertise *Ariva* as "containing lower nitrosamines".

Q: Does the FDA have the authority to regulate this product?

A: No. *Ariva* is a **smokeless tobacco product**. Smokeless tobacco products come in a variety of forms. Star produces three forms of smokeless products using StarCured™ tobacco: Stonewall™ moist snuff, Stonewall™ dry snuff, and *Ariva* compressed powdered tobacco cigarette™ pieces. The Comprehensive Smokeless Tobacco Health Education Act defines smokeless tobacco as "any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity". The tobacco used in *Ariva* is ground and powdered. It also is compressed to provide tobacco users with a product that does not require expectoration. Star is not opposed to **all** tobacco products being regulated by the FDA, and has advocated that Congress take action to give the agency that authority. However, Star is opposed to any efforts to selectively regulate tobacco products.

Q: The Supreme Court has ruled 5-4 that tobacco products do not fall under existing Food and Drug Administration jurisdiction. What is Star's position on FDA regulation?

A: Star has publicly supported comprehensive and fair regulation of all tobacco products since 1999, and publicly expressed its disappointment with the Supreme Court ruling in March 2000. Star will continue to support legislation in Congress that ensures **comprehensive** regulation of all aspects of the manufacturing, labeling, marketing and sale of all tobacco products. While we await Congressional action, Star will continue to

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work diligently to convince others that it is time for a new standard of responsibility among tobacco companies.

Q: Will this product be enticing to children and adolescents ?

A: Each package of *Ariva* includes the following prominent labeling: "Underage Sale Prohibited", and "This Product is for Adult Tobacco Users Only". *Ariva* will be sold under the same rules, regulations and requirements that govern all tobacco products. Star supports national, state and local governmental efforts to enact the most stringent laws designed to ensure that no tobacco products are sold to anyone under age. No direct consumer advertising will be used during the test marketing except at point of purchase. In addition Star does not use any kinds of messages, pictorials, etc. which would entice children and adolescents to use the product. The *Ariva* cigaretteTM piece has a tobacco taste that, while not unfamiliar to smokers, has been described as slightly bitter. Post-marketing and monitoring studies will be conducted to determine who is using the product.

Star also has developed innovative packaging for *Ariva* that uses child-resistant blister packs to prevent easy access or use. We believe this is the first time a tobacco product ever has been packaged specifically to prevent young children from gaining access to a tobacco product, notwithstanding the fact that poison control data indicates that there are roughly 8000 reported incidents of toxic illness each year resulting from toddlers or young children consuming tobacco products, cigarette butts or whole cigarettes.

Q: One of the pharmaceutical companies is reported to have introduced a nicotine lozenge in England that is intended to be used as a smoking cessation tool. What is the difference between that product and *Ariva*?

A: *Ariva* is not a cessation product. Star Scientific's principal mission is to develop technologies and tobacco products that reduce toxins. Star's objective is to give adult tobacco users, and particularly smokers, an alternative tobacco product--- one that (1) uses StarCuredTM tobacco and (2) is not combusted. Tobacco is a legal product, and Star believes that new, potentially beneficial tobacco products must be developed and marketed whenever such products are technologically feasible.